UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: September 9, 2020

SUBJECT: Efficacy Review for Monofoil D,
EPA Reg. No. 90856-4
DP Barcode: 458547
E-submission No. 52270

FROM: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: September 9, 2020

TO: Jacqueline Hardy, PM 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Apply Guard, LLC

Formulation from the Label:

Active Ingredient(s)	% by wt.
3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride	0.13%
N-Alkyl Dimethyl Benzyl Ammonium Chloride (60% C14, 30% C16, 5% C18, 5% C12)	0.25%
N-Alkyl Dimethyl Ethylbenzyl Ammonium Chloride (68% C12, 32% C14)	0.25%
Other Ingredients	99.37%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: Label Amendment

Currently registered efficacy claim(s): Hospital / healthcare disinfectant (bactericidal) for hard nonporous surfaces

Requested action(s): Adding 2 viruses to the label and emerging viral pathogen claims

Documents considered in this review:

- Cover letter from applicant to EPA dated May 6, 2020
- Letter from applicant withdrawing viral studies to qualify for expedited review
- Terms of Registration, not dated
- Proposed label dated 8/18/2020
- Data Matrix (EPA Form 8570-35) dated 7/4/2020
- 2 efficacy studies (MRIDs 51204901 and 51206001)
- Confidential Statement of Formula (EPA Form 8670-4) dated 8/18/2020

II AGENCY STANDARDS FOR PROPOSED CLAIMS

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.

2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:

For an emerging viral pathogen that is a/an…	*Qualifying criterion*
Enveloped virus emerging viral pathogen	At least one large OR one small non-enveloped virus
Large, non-enveloped emerging viral pathogen	At least one small, non-enveloped virus
Small, non-enveloped emerging viral pathogen	At least two small, non-enveloped viruses with each from a different viral family

III PROPOSED DIRECTIONS FOR USE

"Hard Surface: Spray Shake well. Shake well. (This product) comes ready to use. Spray directly onto surface, spray entire surface area 4"-6" from hard, non-porous surface until completely wet; surface must remain wet for 10 minutes and then allow to air dry. (To Disinfect) (For 10-minute Bacteria disinfection*): Let stand for ten (10) minutes then allow to air dry."

IV STUDY SUMMARIES

1.	**MRID**	51204901		
Study Objective		Disinfectant - virucidal		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc. ID1016-101		
Experimental Start Date		6/3/20	**Study Completion Date:**	6/26/20
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Severe Acute Respiratory Syndrome-Related Coronavirus 2, (SARS-CoV-2) (COVID 19 Virus), Strain: USA-WA 1/2020, Source: BEI Resources, NR-52281		
Indicator Cell Culture		Vero 6 cells (ATCC CRL-1586		

Test Method		ASTM International E1053-20 "Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces"
Application Method		RTU Liquid; 2.0 mL
Test Substance Preparation	**Name/ID**	MonoFoil D
	Lots ☐ **1** ☐ **2** ☒ **3**	042920001, 042920002, 051120001
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: N/A
Soil load		5% FBS
Carrier type, # per lot		Glass petri dish, 1
Test conditions		Contact time: 3 minutes; Temperature: 21°C; RH: 48%
Neutralizer		MEM + 10% NCS + 0.5% Lecithin+ 0.5% Polysorbate-80
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: Corrected typographical error on pages 2 and 13: The Protocol references the test method "ASTM E1053-11". It should be updated to reflect the newest method date "ASTM E1053-20".

2.	**MRID**	51206001		
Study Objective		Disinfectant - virucidal		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; ID 1016-105		
Experimental Start Date		6/18/2020	**Study Completion Date:**	6/30/2020
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Human rotavirus, Strain WA (ATCC VR-2018)		
Indicator Cell Culture		MA-104 cells (Charles River Laboratories)		
Test Method		ASTM International E1053-20 "Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces"		
Application Method		RTU Liquid; 2.0 mL		
Test Substance Preparation	**Name/ID**	MonoFoil D		
	Lots ☐ **1** ☒ **2** ☐ **3**	042920001, 042920002		
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: n/a		
Soil load		5% NCS		
Carrier type, # per lot		Glass petri dish, 1		
Test conditions		Contact time: 3 minutes; Temperature: 21°C; RH: 57-60%		
Neutralizer		MEM + 10% NCS + 0.5% Lecithin+ 0.5% Polysorbate-80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments:Corrected typographical error on pages 2 and 13: The Protocol references the test method "ASTM E1053-11". It should be updated to reflect the newest method date "ASTM E1053-20".		

V STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot 042920001	Lot 042920002	Lot 051120001	
3 minutes, RTU spray, 5% soil load						
51204901	Severe Acute Respiratory Syndrome-Related Coronavirus 2, Strain: USA-WA 1/2020, Source: BEI Resources, NR-52281	10^{-2} to 10^{-3} dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity	6.10
		10^{-4} to 10^{-7} dilution	Complete inactivation	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤3.10	≤3.10	≤3.10	
		Log Reduction	≥3.00	≥3.00	≥3.00	
51206001	Human Rotavirus, Strain WA (ATCC VR-2018)	10^{-2} to 10^{-3} dilution	Cytotoxicity	Cytotoxicity	-	6.10
		10^{-4} to 10^{-7} dilution	Complete inactivation	Complete inactivation	-	
		Log_{10} $TCID_{50}$/carrier	≤3.10	≤3.10	-	
		Log Reduction	≥3.00	≥3.00	-	

VI STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51204901	Disinfectant, virucidal	Hard non-porous surface	Liquid; Ready-to-Use	3 minutes	5% FBS	N/A	• Severe Acute Respiratory Syndrome-Related Coronavirus 2, Strain: USA-WA 1/2020, Source: BEI Resources, NR-52281	**Yes**
51206001	Disinfectant, virucidal	Hard non-porous surface	Liquid; Ready-to-Use	3 minutes	5% NCS	N/A	• Human Rotavirus, Strain WA (ATCC VR-2018)	**Yes**
51206001	Emerging Pathogen: -Enveloped Viruses	Hard non-porous surface	Liquid; Ready-to-Use	3 minutes	5% NCS	N/A	• Rotavirus (ATCC VR-2018), Strain: WA	**Yes**

VII LABEL COMMENTS

Label Date: 8/18/2020

1. The proposed label claims that the product, MonoFoil D, when applied as a ready-to-use spray, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 3-minute contact time:

    - Severe Acute Respiratory Syndrome-Related Coronavirus 2, Strain: USA-WA 1/2020, Source: BEI Resources, NR-52281
    - Human Rotavirus, Strain WA (ATCC VR-2018)

    These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, MonoFoil D, qualifies for the following emerging viral pathogens claim:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Large, non-enveloped	Rotavirus WA
Enveloped virus	SARS associated coronavirus, SARS COV 2

These claims are **not acceptable** as written (see section II for acceptance criteria.

Please revise the emerging viral pathogens statement on page 14 of the label exactly as follows:

"This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

-Enveloped Viruses

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Rotavirus (ATCC VR-2018), Strain: WA

Acceptable claim language:

*MonoFoil D has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, non-porous surfaces. Therefore, MonoFoil D can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.*

[Name of illness/outbreak] *is caused by* ***[name of emerging virus].*** *MonoFoil D kills similar viruses and therefore can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on hard, non-porous surfaces. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information.*"

Please revise the Terms of Registration as follows:

- The Terms of Registration should be dated, have the product name and registration number, and include the following statement:

  "Per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels', [Company Name] agrees to the following terms of registration:"

- followed by the four statements from the submitted Terms of Registration.

- Revise statement 3 to remove "large non-enveloped, and/or small non-enveloped" as this product does not yet meet the criteria to make these claims.

- Remove all references to SARS CoV 2 as this is an enveloped virus and cannot be used to support emerging viral pathogen claims.

3. Make the following changes to the proposed label:

   a. Throughout the label,
      i. include a qualifier that links all "COVID-19 virus" claims to full organism name in table "SARS-Related Coronavirus 2". Remove or revise all "COVID 19" claims not clearly linked to the virus. Claims against the disease are misleading and must be removed.
      ii. Include the qualifier "on hard non-porous surfaces" to all claims against SARS-Related Coronavirus 2 or COVID 19 virus.
      iii. Qualify claims such as "multi-action", "multi-purpose", "dual action" with the intended actions (e.g. disinfectant and deodorizer)
      iv. Qualify "germ", "germs", and "germicidal" as appropriate. The label has no fungi listed.
      v. Remove claims for "mold and mildew" or provide supporting 7-day mildewstat data to support label claim.

   b. On page 3 of the label,
      i. Qualify "disinfects as it cleans" with "when used according to disinfection directions for use"
      ii. Remove "everyday protection" as this claim implies residual efficacy.
      iii. Remove "grade" from "hospital-grade" and "healthcare grade" as these claims imply enhanced efficacy per the label review manual.
      iv. Remove claims for "cold and flu viruses". The viruses on the label are not sufficient to support this claim.
      v. Remove "N-List Approved". This claim may imply agency endorsement.

c. On page 4 of the label,
    i. Remove or revise “Power of MonoFoil” as this claim may imply enhanced efficacy. An acceptable alternative may be “the cleaning power of MonoFoil”.
    ii. Remove claim for “disinfects soft surfaces” or provide supporting efficacy data
    iii. Remove “disinfectant shield” claim is this claim is misleading and implies residual efficacy.
    iv. Remove or qualify “surfaces of a wide variety of substrates” with “hard nonporous surfaces” or link to the table of relevant surfaces.

d. On page 5 of the label,
    i. Remove “control” from “Disinfection Control (Formula)”
    ii. Remove “Gives treated surfaces effective protection against many bacteria” as this claim is misleading and implies residual efficacy.

e. On page 6 of the label,
    i. Remove “eliminates the spread” or revise to “reduces cross contamination of [insert claim] between treated surfaces”.
    ii. Qualify “all over your (home) (office)” with “hard nonporous surfaces”
    iii. Remove “protect your house (home) (office)” and “provides effective protection” as this claim implies residual efficacy.

f. On pages 7 and 8 of the label,
    i. Recommend revising disinfection directions for use to indicate surface must remain *visibly* wet for the contact time, as this is a clearer indicator for end users.

g. On page 10 of the label,
    i. Specify “sealed” or “glazed” for “porcelain (tile)” and “(resilent)(ceramic) floor”
    ii. Specify external surfaces of toilets and urinals.